UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ELAINE WANG, Derivatively on Behalf of Nominal Defendant BIOGEN INC.,	)	
Plaintiff,	)	Case No. 1:22-cv-11180
v.	)	JURY TRIAL DEMANDED
MICHEL VOUNATSOS, STELIOS PAPADOPOULOS, ALEXANDER J. DENNER, CAROLINE D. DORSA, MARIA C. FREIRE, WILLIAM A. HAWKINS, WILLIAM D. JONES, JESUS B. MANTAS, RICHARD C. MULLIGAN, ERICK K. ROWINSKY, STEPHEN A. SHERWIN, NANCY L. LEAMING, and BRIAN S. POSNER,	)	
Defendants,	)	
and	)	
BIOGEN INC.,	)	
Nominal Defendant.	)	

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Elaine Wang ("Plaintiff"), by and through her undersigned attorneys, brings this derivative complaint for the benefit of nominal defendant Biogen Inc. ("Biogen" or the "Company"), against its Board of Directors (the "Board") and certain of its executive officers seeking to remedy the Individual Defendants' (defined below) breaches of fiduciary duties and violations of federal law. Plaintiff alleges the following based upon personal knowledge as to herself and her own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of publicly available documents concerning Biogen, transcripts of

conference calls with analysts, announcements concerning the Company, filings with the United States Securities and Exchange Commission ("SEC"), press releases issued by, and regarding, Biogen, legal filings, news reports, securities analysts' reports about the Company, and other publicly available information.

NATURE OF THE ACTION

1. This is a shareholder derivative action brought on behalf of Biogen against certain officers and members of the Company's Board for breach of their fiduciary duties to the Company and its shareholders and violations of federal securities laws during the period June 7, 2021, through January 11, 2022, inclusive (the "Relevant Period"). This action is also brought in connection with the Board's misconduct related to an illegal scheme to pay the copays of Medicare patients taking certain of the Company's drugs, in violation of the Anti-Kickback Statute ("AKS").

2. Biogen is a global biopharmaceutical company headquartered in Cambridge, Massachusetts. The Company focuses on developing therapies for people living with serious neurological and neurodegenerative diseases. Biogen's core growth areas include multiple sclerosis, Alzheimer's disease and dementia, and other chronic neurological diseases and conditions.

3. Beginning as early as 2007, Biogen worked to develop a monoclonal antibody treatment for Alzheimer's disease known as aducanumab and branded as "Aduhelm."[1] During the Relevant Period, the Individual Defendants misled investors as to the commercial readiness of Aduhelm and pressured the United Stated Food and Drug Administration (the "FDA") to approve the drug.

[1] For ease of reference, this complaint uses "Aduhelm" to refer to the treatment, though prior to the FDA's approval it was routinely referred to by the unbranded name, aducanumab.

4. On March 21, 2019, after a futility analysis of Aduhelm's Phase III efficacy trials determined that there was insufficient evidence of a clinical benefit in patients to justify the Aduhelm's submission to the FDA for approval, Biogen discontinued the trials and announced the disappointing results to investors. Biogen's Chief Executive Officer ("CEO"), Defendant Michel Vounatsos ("Vounatsos"), referred to the failure as "evidence of the complexity of treating Alzheimer's Disease and the need to further advance knowledge of neuroscience." On this news Biogen stock plummeted almost 30%, from $320.59 to $226.88 per share.

5. Internally, Biogen executives, hoping to salvage the treatment's commercial prospects, pursued a lobbying campaign with the FDA known as "Project Onyx," to reinterpret the data from the Phase III trials in a more favorable light. According to news reports, as early as April 2019, Biogen's Chief Medical Officer, Defendant Alfred Sandrock ("Sandrock"), reached out to the FDA to determine if there was any path forward for approval, notwithstanding the results of the Phase III trials. The head of the FDA's Division of Neuroscience, Billy Dunn ("Dunn"), was a former colleague of Sandrock and allegedly became an internal advocate at the FDA for Aduhelm's approval.

6. On October 22, 2019, Biogen announced it would be submitting Aduhelm to the FDA for approval as a result of a "new analysis" of the data from the Phase III trials. Biogen completed the submission of Aduhelm for FDA approval in July 2020 and announced that it had begun efforts to identify potential treatment sites across the country and engage with stakeholders to price the treatment.

7. Despite the Company's efforts, on November 6, 2020, the FDA's Peripheral and Central Nervous System Drug Advisory Committee (the "PCNS Advisory Committee") unanimously recommended against approving Aduhelm to treat Alzheimer's disease, based

largely on a lack of demonstrable clinical benefit. Nonetheless, the Company persisted – apparently confident in its improper lobbying campaign with the FDA.

8. By spring of 2021, Biogen had substantially ramped up its nationwide campaign to identify potential treatment sites that would offer the therapy and continued to "educate" healthcare providers and other stakeholders about Aduhelm's benefits. The development of a network of treatment sites was critical to Aduhelm's commercial success once the FDA's anticipated approval of the treatment was confirmed.

9. On June 7, 2021, the FDA approved Aduhelm through its Accelerated Approval process for the treatment of Alzheimer's disease. In public statements the same day, Biogen announced it would price Aduhelm at approximately $56,000 per person, per year. In various interviews, Vounatsos told investors that there were 900 sites ready to start treating patients and Biogen was ready to ship millions of doses. Investors also knew from Vounatsos' prior statements that Biogen had done a "thorough engagement" on price with stakeholders, including private and public payers – a point he emphasized in interviews the same day.

10. The next day, June 8, 2021, in both press releases and during a conference call with investors to discuss Aduhelm's commercial rollout. On the call, and throughout the Relevant Period, the Individual Defendants and made false and misleading statements, or omitted material facts, concerning: (i) the number of sites ready to administer Aduhelm in the near-term; (ii) the significance of logistical constraints on diagnosing potential patients; (iii) the degree to which Medicare's coverage of the treatment was independent of the FDA's approval of the treatment, and not "automatically presumed" following approval; (iv) the willingness of third-party payors to cover Aduhelm absent peer-reviewed data supporting the treatment's clinical effectiveness; and (v) the Veterans Health Administration's (the "VA" or "Veterans Administration") willingness

and capacity to cover and administer Aduhelm for its beneficiaries.

11. Defendants omitted to reveal that, given Anduhelm's unusual approval process and irregular collaboration with the FDA, many healthcare providers were unwilling to provide the treatment at any price until they could see peer-reviewed data supporting the treatment's clinical benefit. A survey published by Bloomberg News on November 18, 2021, for example, revealed that "[n]one of the 25 large insurers that responded to a Bloomberg News survey judged the $56,000-a-year drug 'medically necessary.' Insurers cited uncertainty about benefits and side effects for their denials."

12. By the end of the Relevant Period, Defendants acknowledged that the treatment was not actually available at 900 sites and that sales had been substantially curtailed by bottlenecks relating to the processes for confirming the presence of a plaque known as amyloid beta in potential Aduhelm patients. Further, the Veterans Administration had refused to include Aduhelm in its formulary.

13. On January 11, 2022, after the close of trading, the U.S. Centers for Medicare and Medicaid Services ("CMS") released a draft opinion, limiting Medicare reimbursement for Aduhelm to patients enrolled in ongoing clinical trials – effectively contradicting Biogen's claim that Medicare coverage was automatic following FDA approval.

14. On this news, the Company's common stock price fell $16.18 per share to a price of $225 per share at market close on January 12, 2022.

15. The Company's irregular contacts with the FDA to secure Aduhelm's approval were the subject of two separate articles by STAT News and the *New York Times* published in June and July 2021, respectively. On July 9, 2021, the then Acting Commissioner of the FDA requested the Inspector General of the Department of Human Services to investigate how Aduhelm

received FDA approval, noting there was contact between the FDA and Biogen outside the normal course.

16. Additionally, the unusual process is presently the subject of Congressional investigations, as well an investigation by the Office of the Inspector General of U.S. Health and Human Services. The SEC and the Federal Trade Commission ("FTC") are also investigating Biogen in connection with Aduhelm's approval and marketing.

17. On February 7, 2022, a securities class action was filed against the Company, captioned *Oklahoma Firefighters Pension and Ret. Sys. v. Biogen Inc. et al*, Case No. 1:22-cv-10200-WGY (D. Mass.) (the "Securities Class Action"). On June 27, 2022, plaintiffs in the Securities Class Action filed an Amended Complaint (the "Securities Amended Complaint," 1:22-cv-10200-WGY ECF No. 30), which contains detailed allegations based on interviews with numerous former Biogen employees (referred to as FE 1 – FE 8) who have provided information supporting claims for violations of the Securities Exchange Act of 1934 (the "Exchange Act").

18. Additionally, on December 17, 2020, the United States Department of Justice (the "DOJ") announced that the Company had agreed to pay $22 million to resolve a lawsuit captioned *United States ex rel. Nee vs. Biogen et. al.*, Case No. 17-CV-10192-MLW (D. Mass.) (the "Whistleblower Action"). The complaint in the Whistleblower Action (the "Whistleblower Complaint," 17-CV-10192-MLW ECF No. 1) claims that the Company violated the False Claims Act by illegally paying the copays of Medicare patients taking Biogen's multiple sclerosis drugs, Avonex and Tysabri.

19. According to the DOJ, between 2011 and 2013, Biogen conducted a scheme in violation of the Anti-Kickback Statute ("AKS") by using two foundations as conduits to pay the copay obligations of Medicare patients to induce those patients to purchase Medicare-reimbursed

Avonex and Tysabri prescriptions. As part of the scheme, Biogen identified for its vendor, Advanced Care Scripts ("ACS"), certain patients in Biogen's Avonex or Tysabri free drug program. Biogen then worked with ACS to transfer these patients to the foundations, which received contemporaneous payments from Biogen and then covered the costs of Medicare copays for most or all of these patients.

20. Following the resolution of the claims in the Whistleblower Action, the Company was sued by Humana, a Medicare Part D insurance plan administrator. In a lawsuit captioned *Humana, Inc. v. Biogen, Inc. et al.*, Docket No. 1:21-cv-11578 (D. Mass.) (the "Humana Action"), Humana alleges that Biogen's illegal scheme caused Humana to pay millions of dollars in reimbursements for Tysabri, Avonex, and a third drug, Tecfidera, that it would not have otherwise paid. The Humana Action seeks recovery of Humana's payments which, from 2011 through 2019, totaled over $2.3 billion.

21. In addition to the costs and expenses related to defending itself against the Securities Class Action and the Humana Action and exposing Biogen to potential liability for class-wide damages, the Individual Defendants' misconduct has subjected the Company to costs incurred in connection with wasting of corporate assets, and enabled the Individual Defendants, who were improperly overcompensated by the Company, to unjustly enrich themselves, among other damages. Further, in addition to the costs related to defending itself against the Whistleblower Action, the Individual Defendants' misconduct caused the Company to pay $22 million in connection with settling the claims in that action.

JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and section 27 of the Securities Exchange Act of 1934 (the "Exchange Act") over the claims asserted herein

for violations of sections 10(b) of the Exchange Act and Rule 10b-5 (17 C.F.R.§240.10b-5) promulgated thereunder by the SEC.

23. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

24. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

25. In connection with the acts, conduct and other wrongs complained of herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, the United States mail, and the facilities of a national securities market.

26. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b) because Nominal Defendant Biogen is headquartered in this District and conducts business in this District.

PARTIES

Plaintiff

27. Plaintiff is, and has been at all relevant times, a continuous shareholder of Biogen.

Nominal Defendant

28. Nominal Defendant Biogen is incorporated under the laws of Delaware with its principal executive offices located in Cambridge, Massachusetts. Biogen's common stock trades on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "BIIB."

Individual Defendants

29. Defendant Vounatsos serves as the Company's Chief Executive Officer ("CEO") and has served as a director of the Company since January 2017. According to the Company's public filings, Vounatsos received $17,689,665 in 2021 in compensation from the Company.

30. Defendant Stelios Papadopoulos ("Papadopoulos") serves as Chairman of the Board and has served as a director of the Company since 2008. Papadopoulos also serves as a member of the Board's Corporate Governance Committee. According to the Company's public filings, Papadopoulos received $679,873 in 2021 in compensation from the Company.

31. Defendant Alexander J. Denner ("Denner") has served as a director of the Company since 2009 and is Chair of the Board's Corporate Governance Committee. According to the Company's public filings, Denner received $425,413 in 2021 in compensation from the Company.

32. Defendant Caroline D. Dorsa ("Dorsa") has served as a director of the Company since 2010 and is Chair of the Board's Audit Committee. According to the Company's public filings, Dorsa received $425,413 in 2021 in compensation from the Company.

33. Defendant Maria C. Freire ("Freire") has served as a director of the Company since June 2021 and is a member of the Board's Compensation and Management Development Committee. According to the Company's public filings, Freire received $351,567 in 2021 in compensation from the Company.

34. Defendant William A. Hawkins ("Hawkins") has served as a director of the Company since 2019 and is a member of the Board's Audit Committee. According to the Company's public filings, Hawkins received $410,413 in 2021 in compensation from the Company.

35. Defendant William D. Jones ("Jones") has served as a director of the Company since June 2021 and is Chair of the Board's Compensation and Management Development Committee. According to the Company's public filings, Jones received $361,567 in 2021 in compensation from the Company.

36. Defendant Jesus B. Mantas ("Mantas") has served as a director of the Company since 2019 and is a member of the Board's Corporate Governance Committee. According to the Company's public filings, Mantas received $410,413 in 2021 in compensation from the Company.

37. Defendant Richard C. Mulligan ("Mulligan") has served as a director of the Company since 2009 and is a member of the Board's Compensation and Management Development Committee. According to the Company's public filings, Mulligan received $410,413 in 2021 in compensation from the Company.

38. Defendant Eric K. Rowinsky ("Rowinsky") has served as a director of the Company since 2010 and is a member of the Board's Corporate Governance Committee. According to the Company's public filings, Rowinsky received $410,413 in 2021 in compensation from the Company.

39. Defendant Stephen A. Sherwin ("Sherwin") has served as a director of the Company since 2010 and is a member of the Board's Audit Committee. According to the Company's public filings, Sherwin received $460,413 in 2021 in compensation from the Company.

40. Defendant Nancy L. Leaming ("Leaming") served as a director of the Company from 2008 until June 2022. According to the Company's public filings, Leaming received $435,413 in 2021 in compensation from the Company.

41. Defendant Brian S. Posner ("Posner") served as a director of the Company from 2008 until June 2022. According to the Company's public filings, Posner received $444,108 in 2021 in compensation from the Company.

42. Defendants referenced in paragraphs 29 through 41 are referred to herein as the "Individual Defendants," and, with Biogen, the "Defendants."

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

43. By reason of their positions as officer and directors of Biogen, and because of their ability to control the business and corporate affairs of Biogen, the Individual Defendants owed Biogen and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Biogen in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Biogen and its shareholders so as to benefit all shareholders equally.

44. Each director and officer of the Company owes to Biogen and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligation of fair dealing.

45. The Individual Defendants, because of their positions of control and authority as officer and directors of Biogen, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

46. To discharge their duties, the officers and directors of Biogen were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

47. Each Individual Defendant, by virtue of his or her position as a director and/or officer owed the Company and its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and/or officer of Biogen, the absence of good faith on their part, or a

reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

48. As senior executive officer and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, financial statements, products, management, internal controls, earnings, and present and future business prospects, including the dissemination of false and/or materially misleading information regarding the Company's business, prospects, and operations. The Individual Defendants also had a fiduciary duty to disclose the material information necessary to prevent other public statements, including those in its regulatory filings with the SEC, from being materially false, so that the market price of the Company's common stock was based upon truthful, accurate, and fairly presented information.

49. To discharge their duties, the officers and directors of Biogen were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Biogen were required to, among other things:

(a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware and the United States, and pursuant to Biogen's own Code of Business Conduct (the "Code of Conduct");

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how Biogen conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;

(d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Biogen and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;

(e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Biogen's operations would comply with all applicable laws and Biogen's public statements, financial statements and regulatory filings were accurate;

(f) adequately monitor the Company's officers and employees to ensure their public statements about the Company were complete and accurate;

(g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

50. Each of the Individual Defendants further owed to Biogen and its shareholders the duty of loyalty requiring that they favor the interests of Biogen and its shareholders over their own while conducting the affairs of the Company, and that the Individual Defendants refrain from using

their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

51. Because of their advisory, executive, managerial, and directorial positions with Biogen, each of the Individual Defendants had access to adverse, non-public information about the Company.

52. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Biogen.

BIOGEN'S CODE OF BUSINESS CONDUCT

53. Biogen's Code of Conduct applies to all employees, officers and directors, and "provides the ethical guidelines and expectations for conducting business on behalf of the Company."

54. In a section under the heading "Complete, accurate and timely disclosures and business records," the Code of Conduct states:

> Our Company is subject to extensive and complex reporting requirements. Our operations must comply with all applicable regulatory, accounting, financial, tax and other rules and regulations of the jurisdictions in which we operate.
>
> Business Partners, government officials, investigators and the public rely on the accuracy and completeness of our financial reports, business records and what we tell them. All of our financial records and accounts, and financial statements must be clear and complete, maintained in reasonable detail, and appropriately reflect our Company's transactions and activities. This includes our financial records and operational data such as cost and production data, expense reports and employee records. Accurate and complete information is also essential to us as a basis for sound decision-making.
>
> The Company's filings with the Securities and Exchange Commission, as well as other public disclosures by or on behalf of our Company, must be fair, complete, accurate, timely, and understandable. Our accounting and financial reporting practices must also comply with applicable generally accepted accounting principles and other criteria, such as local statutory reporting and tax requirement. Depending on their positions with the Company, employees may be called upon to provide necessary information to assure that the Company's filings and public communications meet these standards. The Company expects employees to take

this responsibility seriously and to promptly provide current, accurate and complete answers to inquiries related to the Company's public disclosure requirements.

55. In a section under the heading, "We are transparent and ethical," the Code of Conduct states:

> We do not offer or provide improper incentives, kickbacks, or bribes to win business, to influence a business or prescribing decision, or to advance our interests with government authorities. In particular, our interactions with healthcare professionals, government entities, government employees, and others must be legitimate and never to obtain an improper advantage or to improperly influence or encourage a decision by them.
>
> **Cooperating with regulators**
>
> We will always comply with relevant laws and regulations and cooperate with government agencies, law enforcement officials and investigators.
>
> * * *
>
> **Avoiding bribery and corruption**
>
> We do business with honesty and integrity and comply with all applicable ethical and legal standards.
>
> * * *
>
> We are responsible for third parties acting on our behalf. We perform due diligence and carefully monitor our business partners and require them to operate in compliance with our Code and our standards.

56. Additionally, Biogen maintains a Comprehensive Compliance Program ("Compliance Program") to conduct its business "with integrity and ethically[.]"

57. In a section relating to interactions with healthcare professionals, the Compliance Program states:

> In addition, Biogen has adopted policies and practices that govern the full arena of interactions with healthcare professionals. These policies prohibit illegal remuneration in violation of federal and state anti-kickback statutes and incorporate compliance with the PhRMA Code as a key element, including appropriate:
>
> - Support for medical education, as well as the use of healthcare professionals to provide services to the Company as researchers, consultants and speakers.

- Provision of business courtesies.
- Making of grants and charitable contributions so that such funds are not conditioned, express or implied, on any agreement to prescribe, purchase, recommend, influence or provide favorable formulary status for any Biogen product.
- Promotion of Biogen products in compliance with the U.S. Food and Drug Administration's regulatory framework regarding promotion of pharmaceutical products.

BIOGEN'S AUDIT COMMITTEE CHARTER

58. Biogen's Audit Committee Charter, effective December 4, 2019, states that the purpose of the Audit Committee is to assist the Board in its oversight of:

- the integrity of the Company's financial statements;
- the accounting and financial reporting processes of the Company;
- the independence, qualifications and performance of the Company's independent registered public accounting firm;
- the Company's tax strategy and internal audit and corporate compliance functions;
- the Company's financial strategy, policies and practices;
- management's exercise of its responsibility to assess and manage risks associated with the Company's financial, accounting, disclosure, ABAC (anti-bribery and corruption) and distributor matters; and
- the adequacy and effectiveness of the Company's insurance programs.

59. In a section relating to the Audit Committee's authority and responsibilities with respect to financial statements and disclosures, the Audit Committee Charter states that the Audit Committee is to:

- Discuss with management and the independent registered public accounting firm, as applicable, the annual audited financial statements and quarterly financial statements prior to filing, including related disclosures and matters required to be reviewed by the Committee under applicable legal, regulatory or Nasdaq requirements, and such other reports required to be provided by the independent registered public accounting firm under applicable accounting and auditing standards.
- Discuss with management and the independent registered public accounting firm, as appropriate, earnings results, and significant financial disclosure

issues.

- At least on an annual basis, review with management and the independent registered public accounting firm the Company's financial reporting and accounting policies and principles, significant changes in such policies or principles or in their application and the key accounting decisions affecting the Company's financial statements, including alternatives to, and the rationale for, the decisions made.
- Review with management and the independent registered public accounting firm the effect of regulatory and accounting trends, developments and initiatives on the Company's financial statements.
- Review and investigate, as appropriate, matters pertaining to the integrity of the Company's financial statements.
- Establish procedures for confidential and anonymous submission and treatment of complaints regarding the Company's accounting, internal controls, disclosure or other financial or auditing matters.
- Prepare and publish an annual Committee report in the Company's proxy statement in accordance with applicable SEC rules and regulations.

60. In a section titled "Internal Controls," the Audit Committee Charter provides that the Audit Committee:

- At least on an annual basis, review with management and the independent registered public accounting firm the adequacy and effectiveness of the Company's system of internal financial and accounting controls.
- Review with management the Company's assessment of its significant financial, accounting, disclosure, ABAC (anti-bribery and corruption) and distributor risk exposures and steps taken by management to monitor and mitigate such exposures.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

61. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

62. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct were, among other things, to (i) facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty and unjust enrichment; (ii) conceal adverse information concerning the Company's operations, financial condition, future business prospects and internal controls; and (iii) artificially inflate the Company's stock price.

63. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company purposefully, recklessly, or with gross negligence to engage in improper accounting methods, conceal material facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, Individual Defendants collectively and individually took the actions set forth herein. The Individual Defendants described herein were direct, necessary, and substantial participants in the common enterprise, and/or common course of conduct complained here because the action described herein occurred under the authority and approval of the Board.

64. Each of the Individual Defendants aided, abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in or substantially assisted the accomplishment of that wrongdoing and was or should have been aware of his or her overall contribution to and furtherance of the wrongdoing.

65. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and Biogen and was at all times acting within the course and scope of such agency.

SUBSTANTIVE ALLEGATIONS

Biogen's Misconduct Relating to Aduhelm

66. Biogen is a global biopharmaceutical company focused on the research, development, production, and sale of pharmaceutical treatments for serious neurological and neurodegenerative diseases.

67. Beginning as early as 2007, Biogen worked to develop Aduhelm as a monoclonal antibody treatment for patients with Alzheimer's. On March 20, 2015, the Company published results of its Phase I study.

68. Aduhelm purports to reduce the build-up of amyloid beta in the brain, which some research suggests could be an avenue for the prevention and treatment of neurological decline from Alzheimer's disease and dementia. In order to properly test Aduhelm's effectiveness, confirmation of amyloid beta was a prerequisite for an individuals' inclusion in Aduhelm's clinical trials.

69. Confirmation of amyloid beta requires either brain imaging via positron-emission tomography (a "PET scan") or an analysis of cerebrospinal fluid ("CSF") drawn from a lumbar puncture, also known as a spinal tap. Both methods are exceptionally expensive, with PET scans typically costing around $5,000 and ordinarily not covered by insurance, and spinal taps costing between $800 and $1,000.

70. By July 2018, enrollment was completed for the Phase III "ENGAGE" and "EMERGE" studies, designed to evaluate the efficacy and safety of Aduhelm in slowing cognitive and functional impairment in people with early Alzheimer's disease.

71. During the first months of 2019, the Company retained outside experts to examine the Phase III data in a "futility analysis." The futility analysis concluded that neither ENGAGE nor EMGERGE showed sufficient clinical benefit to submit Aduhelm for FDA approval, and that such submission to the FDA would be futile. On March 21, 2019, the Company announced the

results of the futility analysis and its decision to abandon Aduhelm and cease clinical trials immediately.

72. But the Company was determined to not let its significant investment in the therapy go to waste. Despite a lack of data to support Aduhelm's efficacy, Biogen began a lobbying campaign referred to within the Company as "Project Onyx."

73. As early as April 2019, Biogen's Chief Medical Officer, Sandrock, reached out to Dunn, the FDA's Director of the Office of Neuroscience, to discuss the data from the Phase III trials and enlist Dunn's help to push for FDA approval. On June 14, 2019, Sandrock formally met with Dunn regarding submission and approval of Aduhelm. Though such meetings were irregular and against FDA procedures, meetings between representatives of Biogen and the FDA continued regularly though October 2019.

74. On October 22, 2019, in a reversal from its prior statements, Biogen announced in an earnings call that the Company would seek FDA approval for Aduhelm. Biogen justified the reversal as being based on discussions with the FDA and what Defendant Vounatsos described as "additional analysis" of data from the clinical trials. Defendant Vounatsos stated, "[i]n retrospect the result of our futility analysis was incorrect. Based on what we know now it is clear that the pre-specified futility criteria did not adequately anticipate the effect of all the variables in these trials." Sandrock called the decision "a turning point for patients, caregivers, physicians and scientists in the fight against Alzheimer's disease."

75. Biogen completed its submission of Aduhelm to the FDA on July 7, 2020. The submission was announced in the Company's Form 10-Q filed on July 22, 2020. During a conference call and analysts hosted by the Company that day, Defendant Vounatsos announced for the first time that Biogen "[had] started to make progress engaging with payers and defining

[Aduhelm]'s value proposition. And we have now established a cross-functional team dedicated to site readiness, which is currently operational."

76. In November 2020, Dunn and Biogen made a joint presentation to the PCNS Advisory Committee in support of Aduhelm. By a vote of 10 – 0, with one member abstaining, the panel recommended that the FDA not approve Aduhelm based on the lack of proven clinical benefit and safety risks to patients receiving the treatment. Though such advisory committee decisions are not binding on the FDA, the FDA typically heeds its recommendations. Indeed, prior to the FDA's approval of Aduhelm, the agency had never approved a drug or treatment unanimously opposed by such an advisory committee.

77. Still, the Company pushed forward in its campaign. On February 3, 2021, Biogen filed its Form 10-Q with the SEC for the fourth quarter of 2020 and hosted a conference call with investors (the "4Q2020 Earnings Call"). In the 4Q2020 Earnings Call, Defendant Vounatsos stated that the Company remained "ready to launch [Aduhelm] in the U.S., if and when it is approved[,]" and that the Company believed there were "several hundred" sites in the U.S. ready to start treating patients upon approval.

78. Defendant Vounatsos further discussed the work being done to determine the eventual price of Aduhelm:

> Concerning price, we are getting there. We had very large engagements with many stakeholders. And basically, there are 2 main dimensions. The first one is the clinical meaningfulness and potentially in terms of cognitive functions, but also functional aspects on activity of daily living. This is one side of the equation.
>
> The second one is the cost of Alzheimer's to society, which is nowadays more than $550 billion a year in the U.S. The cost for caring for patients, and if I'm not mistaken, it's more than $0.5 million. By the age of 80, 75% of the patients are in nursing home and this costs more than $100,000 a year. And these are the main elements that we consider in our wide engagement on the important topic of price. We are getting there, as I said, but too early to give more specifics.

79. On April 7, 2021, the FDA's Medical Policy and Program Review Council met to discuss approval of Aduhelm and joined the PCNS Advisory Committee's recommendation against approval. Still, Biogen would be informed that FDA staff would come to recommend approval via an "Accelerated Approval" process.

80. On June 7, 2021, the FDA approved Aduhelm under the Accelerated Approval process based on Aduhelm's effects in reducing amyloid beta in patients. Additionally, the FDA approved a broad label for Aduhlem, allowing it to be prescribed to any patient with Alzheimer's disease.

81. In an interview with Bloomberg Business News that same day, Defendant Vounatsos stated that Biogen had already produced millions of vials of Aduhelm, ready to be introduced to the market within two weeks. Vounatsos also stated that "over 900 infusion sites in the U.S. were prepared and ready to administer the drug," which Biogen announced would be priced at $56,000 per patient per year.

82. On this news, the Company's share price skyrocketed, increasing over $100 per share on June 7, 2021, from $295.35 at market open to $395.85 per share at market close.

83. Meanwhile, Aduhelm's approval proved to be controversial. On June 8, 2021, Dr. Joel Perlmutter of Washington University at St. Louis and Dr. David Knopman both resigned from the PCNS Advisory Committee in protest over the approval of Aduhelm. They were joined on June 10, 2021, by Dr. Aaron Kessleheim of Harvard and Brigham and Women's Hospital, who described the approval of Aduhelm as the "worst approval decision the FDA has made that I can remember."

84. The proposed price for Aduhelm proved controversial, too. On June 12, 2021, the advocacy group Alzheimer's Association released a statement deeming Biogen's pricing of

Aduhelm at $56,00 a year as "simply unacceptable."

85. On June 21, 2021, the *New York Times* published an article headlined "Many Alzheimer's Experts Say Use of Aduhelm Should Be Sharply Limited." The sub headline read "[e]ven those who supported the F.D.A.'s approval of the controversial new drug said authorizing it for anyone with Alzheimer's disease was much too broad."

86. On June 22, 2021, the FDA released documents reporting an "internal strife" within the agency relating to the approval of Aduhelm. It was reported by Investor's Business Daily, in an article on June 23, 2021, that "FDA biostatisticians objected to the approval, saying the data didn't support it."

87. On June 25, 2021, Congresswoman Carolyn Maloney of the U.S. House of Representatives Committee on Oversight and Reform and Congressman Frank Pallone of the U.S. House of Representatives Committee on Energy and Commerce jointly announced an investigation of Aduhelm's approval by the FDA and voiced concerns about both the "steep price" and "the process that led to [Aduhelm's] approval despite questions about the drug's clinical benefit."

88. On June 29, 2021, StatNews released an exclusive investigate report regarding Biogen's active lobbying of the FDA for approval of Aduhelm titled, "Inside 'Project Onyx': How Biogen used an FDA back channel to win approval of its polarizing Alzheimer's drug". The efforts centered on lobbying Dunn and the FDA to disregard the negative clinical data from Biogen's Phase III trials that led to Biogen's unfavorable futility analysis. The reporting dubbed Dunn "an inside ally," and noted "the FDA played an extraordinarily proactive role, even drafting a road map on how the company could win approval." According to the report, the FDA recommended Aduhelm be evaluated for approval on its impact on amyloid beta, rather than clinical impact on neurological decline. This approach allowed Biogen to a modest success in reducing amyloid

plaques in some patients as "therapy to reduce the devastating clinical decline and meaningfully change the growth of Alzheimer's disease."

89. On July 9, 2021, Janet Woodcock, the Acting Commissioner of the FDA requested the U.S. Department of Health and Human Services Inspector General's Office ("HHS OIG") to investigate the approval of Aduhelm. In requesting the investigation, Woodcock conceded that there may have been contact between the FDA and Biogen "outside the formal correspondence process."

90. On July 12, 2021, as part of their investigation of Aduhelm, Congresswoman Carolyn Maloney and Congressman Pallone sent a letter to Defendant Vounatsos requesting documents and records regarding Aduhelm's efficacy data and the process by which Biogen communicated with the FDA regarding regulatory approval. The letter contained numerous allegations of improper communications with regulators and questions about Biogen's evaluation of the data used to claim Aduhelm provided a clinical benefit.

91. Also on July 12, 2021, CMS announced the beginning of a National Coverage Determination ("NCD") analysis that would examine whether, and under what circumstances, Medicare would provide coverage for treatments such as Aduhelm.

92. In an article published on July 19, 2021, *The New York Times* reported that it had found "that the process leading to approval took several unusual turns, including a decision for the F.D.A. to work far more closely with Biogen than is typical in a regulatory review." The article further reported there was a "close working relationship [between] the F.D.A. and Biogen . . . during the application process. That included meeting several times a week in the summer of 2019 to jointly assess the data and chart a path forward, as well as a joint Biogen- FDA presentation to a committee of independent experts." *The New York Times* confirmed the STAT News report that

Sandrock met with Dunn to collaborate on a path forward for Aduhelm. Dunn, according to minutes of the meeting, stated that "it is imperative that extensive resources be brought to bear on achieving a maximum understanding of the existing data." One former Biogen employee was quoted as saying they were "shocked by . . . just how close the interaction was between the teams." Former deputy FDA Commissioner and General Counsel for the Department of Health and Human Services, William B. Schultz, was quoted as saying "[i]t is not appropriate for F.D.A. officials to collaborate on publications and presentations with employees of companies with applications pending before those very officials. It undermines the essential arm's-length relationship between the regulator and the regulated industry and destroys the F.D.A.'s credibility…"

93. On August 8, 2021, the HHS OIG's office announced a broad investigation into the FDA's Accelerated Approval process as a result of the approval of Aduhelm.

94. On August 11, 2021, the VA announced that it would not add Aduhelm to its formulary list, effectively foreclosing most veterans as potential patients, citing "a lack of evidence of a robust and meaningful clinical benefit and the known safety signal."

95. The unusual, unorthodox and controversial relationship between the FDA and Biogen concerning the approval of Aduhelm undermined the medical community's trust in the drug and was one significant reason why there was resistance among the medical community to prescribe the treatment. To many potential prescribers, the unusual process underscored the need to independently analyze peer-reviewed data before prescribing the drug.

The Individual Defendants' False and Misleading Statements

96. Following the FDA's approval of Aduhelm, Defendants made false and misleading statements concerning: (i) the number of sites ready to administer Aduhelm immediately after approval; (ii) the significance of logistical constraints on diagnosing patients; (iii) the degree to

which Medicare's coverage of the treatment was independent from the FDA's approval of the treatment; (iv) the willingness of third-party payors to cover Aduhelm absent peer-reviewed data supporting the treatment's clinical effectiveness; and (v) the VA's willingness and capacity to cover and administer Aduhelm for its beneficiaries.

97. On June 8, 2021, Biogen hosted a conference call with investors and analysts to discuss the FDA approval of Aduhelm and the Company's plans for the treatment (the "June 8, 2021, Conference Call").

98. During the June 8, 2021, Conference Call Vounatsos described the work done by Biogen to evaluate sites for the administration of Aduhelm following FDA approval:

> ***Based on our work to date, we estimate there are over 900 sites ready to implement treatment with ADUHELM shortly after approval.*** These sites include clinical trial centers with currently confirmed amyloid beta positive patients as well as other sites with the necessary infrastructure to diagnose and treat patients. [Emphasis added].

99. Biogen U.S. President, Alisha Alaimo ("Alaimo") then stated, with respect to the number of sites ready to treat patients:

> Now the really great news is that we expect a core group of these sites that they will be ready to move really quickly. ***Now we believe, and you heard Michel say, that there are over 900 accounts ready. Let me tell you what ready means. Ready means that they have the required capability, infrastructure, education and, most importantly, willingness to treat a patient with a potential new Alzheimer's therapy***. Now that ADUHELM has been approved, we have local teams throughout the entire country that will prioritize the 900 accounts to support site activation, while our expectation is that more sites are going to become ready in parallel. And our teams are laser-focused on getting this product to as many appropriate patients as possible. [Emphasis added].

100. The statements above were false and misleading when made. As discussed in further detail below, Vounatsos knew or recklessly disregarded that many sites that Biogen had internally deemed as "ready" were not actually independently evaluated. Rather, many of the sites listed by Biogen as "ready" lacked the facilities, infrastructure and/or personnel necessary for the

administration of Aduhelm. Some sites, such as those run by the VA, were included as "ready-to-treat" despite lacking onsite neurologists and despite outright refusing to allow for onsite inspection by Biogen personnel as a result of the COVID-19 pandemic. Even still, certain sites such as Tufts Medical Center were still internally coded as ready despite the fact that they had expressly refused to administer Aduhelm. Vounatsos knew, or recklessly disregarded, that many sites would still require a Pharmacy and Therapeutics Committee review (a "P&T Review"), which could only occur until after FDA approval of Aduhelm.

101. During the June 8, 2021, Conference Call, Defendant Vounatsos described the potential bottlenecks in commercialization:

> ***[T]he desire to confirm amyloid beta pathology by physicians could be a major bottleneck. With this in mind, we have established a program with Labcorp and Mayo Clinic Laboratories to help physicians and patients access CSF diagnostic laboratory testing to aid the diagnosis of Alzheimer's disease.*** And we continue to advocate for PET reimbursement from CMS, joining a coalition of health care organization who supports a revised coverage policy. [Emphasis added].

102. During the June 8, 2021, Conference Call, Alaimo added, with respect to bottlenecks:

> The necessity of testing, as Michel has said, has been left to the judgment of the prescribing physicians. And as the label states, ADUHELM is an amyloid beta-directed antibody. Since there hasn't been an approved therapy that is amyloid beta-directed, amyloid confirmation isn't a routine clinical practice of today, and there is currently no reimbursed test for amyloid. Therefore, the majority of patients have not yet been amyloid confirmed.
>
> But Biogen believes access to this testing should be easily available and affordable. ***Therefore, we've established a program, as you heard Michel say in his opening remarks, with Mayo Clinic Labs and Labcorp to help physicians and patients access cerebrospinal fluid diagnostic laboratory testing.*** Also, as Michel had referred to, we are continuing to work with a coalition of health care and advocacy organizations to support a pathway to PET reimbursement from CMS, and we believe we will need both the CSF test and the PET reimbursement. [Emphasis added.]

103. These statements were materially false and misleading when made and omitted material facts. Vounatsos omitted to reveal that the true source of the bottleneck when it came to prescribing Aduhelm was not the analysis of the samples, but the reluctance on the part of physicians to require elderly patients to endure the process necessary to collect the samples to begin with. The Company was aware that the need to confirm amyloid beta was effectively a universal requirement for the prescription of Aduhelm, that CSF testing following a lumbar puncture was the only cost-effective method of confirmation, and, critically, that physicians were generally reluctant to prescribe lumbar punctures for elderly patients. Further, many centers were disincentivized to perform lumbar punctures given their lower reimbursement rates. Vounatsos' statement misleadingly suggests that the bottleneck would be meaningfully addressed by arranging for Labocorp and Mayo Clinic labs to analyze the spinal fluid, even though the true roadblock to Aduhelm prescription was getting the samples in the first place.

104. Alaimo's statement similarly emphasizes Biogen's efforts to address the logistical barriers to Aduhelm's prescription by assisting with the laboratory analysis of CSF, and mentions advocacy efforts to expand Medicare coverage for PET scans. Alaimo omits the material fact that physicians raised serious concerns with performing lumbar punctures for elderly patients, and testing sites were reluctant to perform them due to the economic disincentives.

105. During the June 8, 2021, Conference Call, Defendant Vounatsos misrepresented that Medicare coverage was "automatically presumed" following FDA approval:

> The vast majority of Alzheimer's patients in the U.S. are 65 or older. And as a result, most of our patients are expected to be covered by Medicare, either through fee-for-service or Medicare Advantage. ***For Medicare fee-for-service, coverage is automatically presumed with FDA approval.*** We expect most Medicare Advantage plans to define their medical policies within the first several months after launch. Biogen is committed to an equitable launch with a goal of maximizing access for all patients with early stage Alzheimer's disease, including the underserved population with can be disproportionately impacted. [Emphasis

added].

106. The statement above was false and misleading because it inaccurately summarizes the complex regulatory process which could have potentially limited reimbursements for Aduhelm in a variety of ways. Specifically, for physician-administered (Medicare Part B) drugs such as Aduhelm, the reimbursement for Medicare-eligible patients can come through two primary routes: (1) regional Medicare fee-for-service contractors ("MACs"); or (2) Medicare Advantage ("MA") plans. Approximately 65% of Medicare patients are covered by regional MACs, with the remaining ~35% covered by MA plans. Under rules in effect as of January 2020, CMS has the regulatory authority to direct MACs and MAs to consider what treatments are "reasonable and necessary" in the course of coverage determinations.

107. Alternatively, CMS has the option to initiate an NCD, formalizing the requirements for reimbursement across all MAC and MA plans. Contrary to Vounatsos's claim above, the possibility of an NCD for Aduhelm was neither hypothetical nor remote. NCDs are not uncommon in circumstances where a treatment is approved under the Accelerated Approval process by the FDA, where the treatment is expensive, or where there is controversy surrounding a treatment's efficacy, side effects, or safety.

108. Also during the June 8, 2021, Conference Call, Alaimo stated:

> Prior to launch, ***our teams have been working closely with both commercial and government payers.*** And what I can tell you is that our commercial teams will be discussing patients consistent with those studied in ADUHELM's clinical development program with their customers. Now we've already talked about the majority of patients being on Medicare. ***And for Medicare fee-for-service, coverage is automatically presumed with FDA approval, and we expect most Medicare Advantage and commercial plans to define their medical policies, which is in reference to your question, within the first several months after launch.*** [Emphasis added.]

109. Alaimo's statement misled investors by repeating the claim that "for Medicare fee-for-service, coverage is automatically presumed with FDA approval," again omitting to reveal

even the possibility of an NCD. As it would happen, CMS's draft and, later, final NCD with respect to Aduhelm strictly limited reimbursement to individuals enrolled in ongoing clinical studies – effectively eliminating the possibility that the treatment would be a significant commercial success in the near-term.

110. Additionally, on the June 8, 2021, Conference Call, Vounatsos described Biogen's $56,000 yearly price tag for Aduhelm:

> ***In determining the price, we engaged with stakeholders, including clinical experts, health economics, policymakers and payors on ADUHELM***; and we remain true to Biogen's pricing principles.
>
> With this consideration in mind, we have priced ADUHELM at WAC of approximately $56,000 per year for an average patient of 74 kilogram at the full maintenance dose. We expect the cost during the first year to be lower due to the dose titration resulting in an average WAC of approximately $41,000 for an average patient.
>
> Importantly, we have committed to not increasing the price of ADUHELM for the next four years. One critical near- term priority for the launch will be securing payer coverage. The vast majority of Alzheimer's patients in the US are 65 or older. And as a result, most of our patients are expected to be covered by Medicare either through fee-for-service or Medicare Advantage. ***For Medicare Fee-For-Service, coverage is automatically presumed with FDA approval. We expect most Medicare Advantage Plans to define their medical policies within the first several months after launch.*** [Emphasis added.]

111. Vounatsos' statement was false and misleading when made because it suggests that Biogen had advanced communications with Medicare and other public and private payers and that those entities had at least indicated a willingness to pay the $56,000 per patient, per year price for Aduhelm set by Biogen. In reality, Biogen knew that many providers and public payors had expressly refused to make any commitments with respect to Aduhelm until after the FDA had made an approval determination and after peer-reviewed data concerning the treatments clinical effectiveness could be provided. Vounatsos' statements about Medicare coverage being "automatically presumed" were false and misleading for the reasons set forth above.

112. After the announcement on June 7, 2021, Vounatsos, in an interview with CNBC's Power Lunch, attempted to justify Aduhelm's steep price, stating:

> ***The price is set at $56,000 a year, during the normal year after lengthy engagement obviously this is important with scientific leaders, pharmaco-economists, payers, private and public payers.*** These are in line with our pricing principle. This is after two decades of having no innovation. This will allow sustainability of continuing to invest in our rich pipeline that goes beyond Alzheimer's, Parkinson's, ALS, stroke, neuropathic pain and many more. So, we believe this is a fair price. We'll be working very closely with Medicare that is covering 80%, we believe approximately of the epidemiology, in order to secure sustainability of the system. And, and monitor very closely, the dramatization. Moreover, we are committed not to take any price increase during the next four years.
>
> * * *
>
> ***You know Meg, and we're engaging with Medicare and we're engaging with the private payers since quite a long time.*** Do you know that today the cost of Alzheimer's is 600 billion to the US in terms of direct and indirect cost. So, it is time without having really a treatment that addresses a defined pathophysiology of the disease, it is really time now that we invest some resources to treatment. [Emphasis added.]

113. The statement above was materially misleading when made because it suggests that the Company had "lengthy engagement" with Medicare and other public and private payers and that those entities had at least indicated a willingness to pay the $56,000 per patient, per year price for Aduhelm set by Biogen. In fact, Biogen knew that many providers and public payors had expressly refused to make any commitments with respect to Aduhelm until after the FDA had made an approval determination and after peer-reviewed data concerning the treatments clinical effectiveness had been provided.

114. Indeed, on November 18, 2021, Bloomberg News reported on a survey from 25 large private insurers who stated they would not provide coverage for Aduhelm based on its price. According to the news story, "[m]ost have deemed Aduhelm experimental, while some say they're still evaluating it. Insurers cited uncertainty about benefits and side effects for their denials." It

was therefore misleading to suggest that payers would not balk at paying the cost and providing coverage when, clearly, a large number of insurers never made any determination until ultimately deciding against coverage.

115. During the June 8, 2021, Conference Call, Defendant Vounatsos described an impending agreement with the VA relating to Aduhelm, stating:

> We are pursuing value-based contracts with payers such as Cigna to help streamline patient access to treatment. We are working with providers groups such as CVS as well as the National Associate of Free and Charitable Clinics, which have neighborhood-level reach, with the goal of engaging underserved people in their local communities to provide them with education about mild cognitive-impairment and to enable access to cognitive screening. ***And we are working to finalize a multiyear agreement with the Veterans Health Administration in order to support access for veterans.*** [Emphasis added].

116. This statement was materially false and misleading because, as discussed in detail below, Biogen knew that key opinion leaders within the VA opposed including Aduhelm in the VA's formulary as early as March 2021.

117. Also on the June 8, 2021, Conference Call, Alaimo stated:

> Now we do believe patients should have access to ADUHELM, which is why innovative contracting is an important part of our launch approach. ***We have engaged, as you might have seen in our press release, with a small number of strategic partners, including Cigna and the Veterans Health Administration, on innovative or value-based contracting.*** For example, Cigna and Biogen intend to enter into a value-based contract to ensure there is a streamlined path to access treatment for patients consistent with the population in which ADUHELM was studied. ***And with the VA, we are finalizing a multiyear agreement in order to support access to ADUHELM for veterans who are historically underserved and racially diverse.*** [Emphasis added].

118. Alaimo's statements above were false and misleading because rather than acting as Biogen's "strategic partners," VA representatives across the country refused to meet and discuss Aduhelm with Biogen. At least one high-level VA opinion leader had expressed opposition to including Aduhelm in the VA's formulary. Indeed, the VA announced, on August 11, 2021, that it would not add Aduhelm to its formulary list citing "a lack of evidence of a robust and meaningful

clinical benefit and the known safety signal."

119. Taken together, Defendant's statements shortly after Aduhelm's approval created the false impression that the approval of Aduhelm by the FDA was the last obstacle to the widespread treatment at a premium price-point. Investors were led to believe that the treatment would be available to patients at hundreds of sites across the country, that bottlenecks to prescribing the treatment had been resolved, that Medicare's coverage was "automatic," that there was widespread support for the treatment's $56,000 per patient, per year cost, and that the VA and Biogen would shortly be entering a multi-year agreement to cover the cost of the treatment for eligible veterans. None of this was true.

120. The gradual revelation of the truth was spurred by several factors – most notably ongoing concern about the treatment's effectiveness, price, and questions about the FDA's approval process which led to the reluctance of physicians to prescribe the treatment. Many of the corrective disclosures identified herein are partially corrective and Defendants continued to mislead investors regarding Aduhelm.

121. On June 23, 2021, the Company issued a press release stating, in relevant part, that it stood "ready to work with public and private payers to address pricing in order to achieve both patient access and support budget sustainability." The press release added that the Company was "ready to work with payers, including CMS, to create innovative agreements which could lower patient co-payments or out-of-pocket expenses for patients treated with ADUHELM."

122. According to a June 23, 2021, Bloomberg story, titled "Biogen Expects Slow Alzheimer's Drug Uptake, May Reset Price," the Company's disclosures were "[a] signal that the drug maker wants to tamp down the outcry over the treatment's potential cost to the U.S. health-care system."

123. Also on June 23, 2021, *The Boston Globe* reported that Tufts Health Plan and Harvard Pilgrim Health Care issued a statement saying the price of Aduhelm should be reduced by as much as a factor of 10 for the drug to be covered by the health plan.

124. On this news, Biogen's stock price fell over 6%, from its closing price on June 23, 2021 of $371.90 per share to close at $349.16 per share on June 24, 2021.

125. On July 8, 2021, the FDA changed the prescribing label for Aduhelm, considerably narrowing its recommended use to only those patients in the early stages of the disease.

126. On July 12, 2021, a survey of Blue Cross Blue Shield ("BCBS") plans conducted by Formulary Watch showed that BCBS plans in in North Carolina, Michigan, Western New York, and Kansas had all refused to cover reimbursement for Aduhelm, deeming the treatment "investigational."

127. On July 15, 2021, the Cleveland Clinic and Mt. Sinai hospital each made announcements stating they would refuse to prescribe Aduhelm. As reported by Bloomberg News in an article dated July 15, 2021, "Biogen's shares sank to their lowest in more than a month after two major hospitals [Cleveland Clinic and Mount Sinai] and a group of health insurers said they wouldn't administer its controversial Alzheimer's disease medicine." In the article, Bloomberg further noted that "a number of Blue Cross Blue Shield providers have said they won't cover the controversial treatment".

128. On July 22, 2021, Biogen held a conference call to discuss the Company's financial results from the second quarter of 2021 (the "2Q2021 Earnings Call").

129. On the 2Q2021 Earnings Call, Defendant Vounatsos stated:

> ***Of the 900 sites approximately which we expected to be ready shortly after approval, we estimate that approximately 325 or 35% have completed a P&T review with a positive outcome or indicated that they won't require a P&T review.*** We have also seen some sites leverage external infusion centers in the face internal

> resistance or are waiting clarity on their facilities internal process. We continue to believe that consistent with our clinical trials, more specialists will require confirmation of amyloid beta pathology, either via PET or CSF, which is also taking time to schedule and coordinate. [Emphasis added].

130. The above statement serves as the first partial admission by Biogen that its previous description of sites as "ready-to-treat" was misleading and not reflective of their actual status. Vounatsos' description of the P&T Review is, in fact, an acknowledgement that despite having claimed these sites were "ready-to-treat" patients, serious evaluation of Aduhelm was still occurring at many sites such that, as of June 8, 2021, they were not "ready to treat."

131. Additionally, Vounatsos' claim that "we believe more specialists will require confirmation for amyloid beta pathology, either via PET or CSF, which is also taking time to schedule and coordinate," misled investors about the reality. First, providers were not using PET scans to confirm the presence of amyloid beta, because there was no reimbursement for the costly procedure. The need for a lumbar puncture, meanwhile, served as either a bottleneck to treatment due to issues regarding capacity of testing facilities or lack of reimbursement, or a firm barrier to having a patient screened due to the risks of lumbar punctures for elderly patients.

132. With respect to Aduhelm's price, Vounatsos then stated on the 2Q2021 Earnings Call that:

> In terms of reimbursement, it is still the early days. And I am pleased to say that we have seen the first examples of Medicare Advantage plans approving pre-authorization. We welcome the recent opening of the National Coverage Determination analysis by CMS for monoclonal antibodies targeting amyloid-beta, including ADUHELM. We believe this process will provide additional clarity on coverage for Medicare beneficiaries and drive consistency of access across the country. We expect that regional Medicare Administrative Contractors and Medicare Advantage plans will provide coverage for ADUHELM while the NCD analysis is underway. We believe that CMS's swift decision to initiate the NCD analysis is a testament to the large unmet need in Alzheimer's disease and the urgency to clarify access for patients.

133. The statement above was a partial corrective disclosure to Vounatsos' earlier misstatements regarding Medicare coverage but continued to be misleading. Vounatsos partially conceded the reality that, contrary to the Company's prior statements, reimbursement for Aduhelm was not "automatically presumed" for Medicare following FDA approval and that Medicare had the ability to limit coverage, contrasting earlier statements by Vounatsos and Alaimo on the June 8, 2021, Conference Call. Still, Vounatsos misled investors by claiming that Biogen "expect[s] that regional Medicare Administrative Contractors and Medicare Advantage plans will provide coverage for Aduhelm while the NCD analysis was underway," despite Biogen's employees experiencing strong pushback and skepticism from networks.

134. Also on the 2Q2021 Earnings Call, in response to a question from Michael Yee of Jeffries on the progress of treating patients a month after approval, Alaimo stated:

> You might have seen recently published several AD specialists recently said, building this infrastructure for the appropriate use of ADUHELM will require time, resources, and some creative planning. In fact, I recently just visited several sites, and what I saw, is consistent with what we're seeing across the entire country. Sites are currently, right now, developing their protocols. They are reengaging with their patients. They are considering or scheduling amyloid-beta confirmation. They also are ordering baseline MRIs. Then, they are discussing these results of the tests and making the treatment decision with their patients. This has clearly taken quite a bit of time. On our last call with you, we shared a program that we created with Labcorp and Mayo Clinic Labs to help physicians and patients access CSF diagnostic laboratory testing. ***We are also seeing a very strong interest in this program.*** In fact, we've already seen the first orders come in for both of our lab partners. Sites are also trying to gain clarity, as you said, on the reimbursement pathway. The decision by CMS to open an NCD analysis will help provide additional clarity to sites and healthcare. [Emphasis added.]

135. The statement above serves as a partial corrective disclosure as to the number of sites that were ready to treat patients, but also continued to create a misleading impression of Aduhelm's progress and challenges. Despite previously representing that there were 900 sites "ready-to-treat," Alaimo revealed that "[s]ites are currently, right now, developing their protocols."

136. Alaimo's descriptions of the challenges misled investors with regard to the bottleneck which was causing physicians to not prescribe Aduhelm for their patients. In describing the "very strong interest" Biogen saw in the program it created with Labcorp and Mayo Clinic Labs for CSF testing, Alaimo failed to disclose that the need for elderly Alzheimer's patients to get a lumbar puncture in order to determine their candidacy was acting as a significant bottleneck.

137. On the 2Q2021 Earnings Call, in describing the status of reimbursement for Aduhelm, Alaimo continued:

> Now, while this analysis is underway, coverage decisions will be made by Regional Medicare Administrative Contractors, as you know is the MACs, and the Medicare Advantage plan. Based on precedent, we expect the MAC s and Medicare Advantage plans will provide coverage for ADUHELM. Now, while NCD for drugs are rare, and the only recent example of a drug NCD analysis, which was CAR-T, both MACs and Medicare Advantage plans continued to cover these -- this product during the NCA process.
>
> We can also confirm that some Medicare Advantage plans have already approved prior authorizations for ADUHELM. For the MACs, due to the miscellaneous coding, it does take them a little bit of time to process the claims, but we are also aware that MACs have received claims already. So during the NCD analysis, we are actively working with sites to support patient access and reimbursement. Keep in mind, and as I witnessed across the various sites that I visited, each site will operationalize at different rates, which is why patient infusions will build gradually over the year as we've referenced. Though this process will take time, it was absolutely humbling to see how much effort and passion these physicians are putting into building the infrastructure to treat their patients and I'm really proud of how hard our teams are working to support these sites as they break new ground.

138. The statement above was misleading, as Medicare Advantage plans are run by private insurance companies, and private insurers were balking at Aduhelm's price and denying coverage.

139. In response to a question from Phil Nadeau of Cowen and Company on the 2Q2021 Earnings Call, Alaimo stated:

> Since PDUFA, we have continued to hear a high level of interest in our ABC program, which I talked about prior, which is the CSF testing, which you heard me talk about in my first answer. Now, the reason why there is a high interest is

> primarily due to three reasons. First, we're hearing a consistent message from the AD experts and the clinicians, that they will align their patient selection to the patient population studied in our clinical trials.
>
> So 100% of patients in our clinical development program were confirmed for amyloid plaques. However, just so you also know, no one's really come out with the policy yet, so I can't actually tell you that there's been a mandate on amyloid-beta confirmation, but we would expect that, potentially, those will be on the policies. Second, there's currently no reimbursed test to confirm the presence of amyloid, in this program that we offer as a solution to provide access to patients who would otherwise lack the ability to pay for this lab test, let alone the cost of a PET scan.
>
> And as you know, for PET scanning third, there are still several areas of the country, in particular the Mountain West, Hawaii, and Alaska, where access to amyloid PET is not available due to the distribution of radio pharmacies and limited half-life of the radioligand. But I also said in our prior call that we do need both PET and CSF and we have seen these orders come in for both of our lab partners, and so we're still working diligently with a coalition to see if we can get PET reimbursement through CMS.

140. This statement was materially misleading, as Alaimo omitted to reveal that opposition to a lumbar puncture was a major bottleneck in physicians' determinations of whether their patients had amyloid beta. Alaimo's statement that "there's currently no reimbursed test to confirm the presence of amyloid, in this program that we offer as a solution to provide access to patients who would otherwise lack the ability to pay for this lab test, let alone the cost of a PET scan" was similarly misleading, as the bottleneck to Aduhelm prescriptions was not the lack of reimbursement for the spinal tap, but the strong opposition to sending elderly dementia patients for lumbar punctures. Few facilities performed a large number of lumbar punctures, the reimbursement structure disincentivized expanding capacity, and few providers wished to subject their patients to the procedure. Biogen's program to cover the cost of analyzing the CSF resulting from lumbar punctures did nothing to alleviate those issues.

141. Also on July 22, 2021, Sandrock posted an "open letter" on the Company's website defending the FDA approval of Aduhelm. In the letter, Sandrock wrote that the approval "came

after an extensive development, testing and review process." Sandrock stated that "ADUHELM'S approval has been the subject of extensive misinformation and understanding. It is normal for scientists and clinicians to discuss data from experiments and clinical trials, to debate, and to disagree, on the interpretation of data." Sandrock continued, "[i]t is important to recognize that collaboration between industry and regulatory agencies is common, appropriate and beneficial." With respect to the scrutiny surrounding the approval, Sandrock added, "[s]eparately, we have seen statements that all of ADUHELM'S results are 'post hoc' – in other words, that a filter was applied after the fact to interpret data in a certain way. That is also factually incorrect."

142. Sandrock's statement that Biogen's interactions with the FDA to resurrect Aduhelm were appropriate and not out of the ordinary was materially false and misleading. Indeed, Acting FDA Commissioner Woodcock, when requesting an investigation by the HHS OIG, conceded there had been contact between the FDA and Biogen "outside the formal correspondence process."

143. On July 27, 2021, Axios reported that Biogen had withdrawn peer-reviewed data from submission to the *Journal of the American Medical Association* after the journal requested significant edits to the paper.

144. On September 9, 2021, Vounatsos and Alaimo attended the Morgan Stanley Global Healthcare Conference (the "Morgan Stanley Conference"). In discussing sales of Aduhelm, Vounatsos stated:

> Although we are facing some near-term challenges and everybody can see that, we continue to see a very high level of physician and patient interest and continue to believe the mid-to long-term opportunity remains significant. In addition to the launch, in the U.S. Aduhelm is now filed in many geographies, and we are pleased to report the recent regulatory approval in the UAE . . . We all know that in the past, some drugs directed to the same hypothesis and the same target did not show benefit. But we all know that these prior drugs did not lower the amyloid plaque, and this is the key difference. And maybe one of the reason of the polemic we hear. However, nowadays there is clearly too much confusion, misinformation and controversy surrounding our data and the approval process. I can tell you, Biogen

> stands behind our clinical data for the 8 studies with more than 3,000 patients that supported the accelerated approval, and we stand behind the integrity of the review process. . . Although our launch is slower than we initially anticipated for all the reasons you know, we are encouraged.

145. Also at the Morgan Stanley Conference, Alaimo stated that "as of this week, we are now aware of approximately 50 sites that are infusing Aduhelm." In discussing continual challenges to commercialization, Alaimo stated:

> In addition, some sites are waiting for our published manuscript before they conduct their P&T reviews, which brings me to the second challenge. During our last earnings call, we shared that sites are in the process of P&T committees. And since that call, we have seen more progress with these formulary decisions. However, after this decision, we are seeing sites experience several operational issues that they need to work through before they can infuse their first patient. And though we did anticipate it would take time, operationalization, the patient journey care pathway is taking longer than we expected.

146. The above statements partially corrected previous misrepresentations that there were 900 sites "ready to treat" patients with Aduhelm. Further, Alaimo noted for the first time than many providers were refusing to move forward with P&T reviews at all without Biogen's peer-reviewed data from the clinical trials being published.

147. In response to a question regarding reimbursement for diagnostic tests for Aduhelm by Matthew Kelsey Harrison of Morgan Stanley, Vounatsos stated:

> This is a very important bottleneck that we had identified before and now that has impacted -- impacting the patient journey even more than what we anticipated. And we have partnership with Labcorp, and we have partnership with the Mayo Clinic, and we see the number of LPs increasing. But certainly, if we could get that reimbursed the way it is for oncology, this will certainly accelerate.

148. This statement was materially misleading when as the barrier to more lumbar punctures was a combination of physical capacity of treatment sites and their willingness to perform lumbar punctures, and providers' unwillingness to subject elderly patients to the procedure. This was compounded by the fact that during all relevant times, CSF analysis via lumbar puncture was the only practical method to confirm amyloid beta. Vounatsos' reference to

the program with Labcorp and the Mayo Clinic does not address the actual sources of the bottleneck, that diagnostic centers performed few lumbar punctures, and doctors did not wish to prescribe them.

149. On November 15, 2021, the Company announced Sandrock's resignation. As a vocal advocate of Aduhelm and its process to gain FDA approval, the timing of Sandrock's resignation raised serious concerns among investors and analysts.

150. On November 17, 2021, the Company announced that the European Medicines Agency ("EMA") was unlikely to approve Aduhelm for patients in the European Union.

151. On November 22, 2021, safety data published in the *Journal of the American Medical Association (JAMA) Neurology* showed that 41% of patients taking Aduhelm experienced either bleeding or swelling in the brain. According to Bloomberg Business News, the study showed that "[a] total of 41% of patients had either brain swelling, bleeding or both. Of those cases, 14 were judged to be serious, including some people who were hospitalized."

152. On December 20, 2021, Biogen announced it was cutting the price of Aduhelm in half, to $28,200.

153. Also on December 20, 2021, the EMA's the Committee for Medicinal Products for Human (the "CHMP") officially rejected Aduhelm for approval in the European Union.

154. On December 22, 2021, the Company announced that regulators in Japan were also unlikely to approve Aduhelm, furthering dampening the therapy's commercial prospects.

155. On January 11, 2022, CMS announced its draft decision on reimbursement for Aduhelm. CMS proposed to cover reimbursement under "Coverage with Evidence Development," limiting reimbursement only to patients enrolled in a clinical trial. Further, the decision limited reimbursement to patients with mild forms of cognitive impairment or mild dementia and,

critically, those who already had amyloid plaques. The relatively severe restrictions imposed a harsh limitation on the potential patient population eligible for reimbursement. In a further blow, private insurance providers often follow the guidance of CMS for their own coverage decisions.

156. On this news, Biogen's stock price plunged from a closing price of $241.52 per share on January 11, 2022, to a close of $225.34 per share on January 12, 2021.

The Truth Emerges

157. On February 4, 2022, Biogen announced that both the FTC and SEC were investigating the Company over its claims regarding "healthcare sites," the FDA's approval of Aduhelm, and the marketing of the treatment.

158. On March 16, 2022, Biogen published the results of the Phase III studies at the International Conference on Alzheimer's and Parkinson's Diseases.

159. On May 3, 2022, Biogen announced that Defendant Vounatsos would be stepping down as CEO of Biogen until a successor could be appointed. At the same time, Biogen announced it was functionally ending its attempts to commercialize Aduhelm, terminating all employees responsible for sales and marketing of the treatment. *The Wall Street Journal* reported that "[t]he company will substantially eliminate the sales infrastructure it built to support Aduhelm's launch, including employees to promote the drugs to doctors and provide logistical assistance for navigating the complex process of administering it to patients" noting that "the cuts will comprise the bulk of an estimate $500 million in annual savings that the company is targeting." *The Wall Street Journal* report added that "[s]ome analysts had expected Aduhelm would help transform Biogen, diversifying its product suite," but noted, "doctors disagreed about the drug's effectiveness, utility and cost, which was initially set at $56,000 annually before being slashed in half in response to criticism."

160. The Securities Amended Complaint includes information from detailed interviews with former Biogen employees, who are described with sufficient detail to establish their reliability and personal knowledge. Specifically, the Securities Amended Complaint provided:

> Former Employee 1 ("FE 1") was an Alzheimer's Account Manager at Biogen from April 2020 until the Aduhelm program was shut down in May 2022. They covered territory in the mid-western part of the country. Their job responsibilities included educating and evaluating treatment sites in order to allow for patients to be treated as quickly as possible after Aduhelm's approval. Any location that was evaluated was referred to as a "treatment site" by Biogen. These were infusion sites, hospital health systems, imaging centers, private neurology practices, and pain clinics.
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> * * *
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> Former Employee 2 ("FE 2") was also an Alzheimer's Account Manager. FE 2 worked with FE 1 in the mid-western part of the country. Like FE 1, their job responsibilities included educating and evaluating treatment sites in order to allow for patients to be treated as quickly as possible after Aduhelm's approval. As with FE 1, the treatment sites FE 2 evaluated included infusion sites, hospital health systems, imaging centers, private neurology practices, and pain clinics.
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> * * *
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> Former Employee 3 (FE 3) was an Access and Reimbursement Manager for Biogen from October 2020 to November 2021. Their job responsibilities included evaluating infusion site assessments. As noted above, Aduhelm is a treatment that must be administered via intravenous infusion. FE 3's assigned territory was in Central California and Las Vegas, Nevada. They were one of 130 similar employees across Biogen's U.S. operation. FE 3 was not part of the sales team.
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> * * *
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> Former Employee 4 ("FE 4") worked as a Director of Account Liaisons from March of 2020 to April 2021. Their responsibilities involved overseeing Account Liaisons in their work assessing site readiness. This involved meetings with employees of various treatment sites to measure that site's "Willingness, Readiness, and Scalability."
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> * * *
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> Former Employee 5 ("FE 5") worked as a Senior Territory Business Manager for Alzheimer's Disease from August 2020 to January 2022. They were responsible for "clinical selling" of Aduhelm. This involved working with doctors directly to convince them to prescribe Aduhelm to patients.
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> * * *
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> Former Employee 6 ("FE 6") worked as a Territory Business Manager in the Boston area from August 2020 until February 2022. FE 6's responsibilities included the "clinical selling" of Aduhelm to providers, who would then prescribe the treatment

> to patients.
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> * * *
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> Former Employee 7 ("FE 7") worked as a Senior Territory Business Manager from August 2020 to March 2022. As with FE 6, FE 7 was responsible for the "clinical selling" of Aduhelm to providers. They reported to Regional Manager Marcy Ross, who in turn reported to Division Manager Kevin Clifton, who report to Vice President Angie McEvoy. McEvoy reported to Deb Glasser.
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> * * *
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> Former Employee 8 ("FE 8") worked as Senior Territory Business Manager for the Alzheimer's Disease business unit from August 2020 to March 2022. FE 8 work was focused on the mid-Atlantic. FE 8 worked directly with potential prescribers of Aduhelm, including neurologists at private medical practices and the outpatient clinics of major hospitals.

(Securities Amended Complaint, ¶¶ 86, 106, 120, 129, 141, 151, 155, and 159).

161. These former employees provided information concerning: (i) the number of sites ready to administer Aduhelm immediately after approval; (ii) the significance of logistical constraints on diagnosing patients; (iii) the degree to which Medicare's coverage of the treatment was independent from the FDA's approval of the treatment; (iv) the willingness of third-party payors to cover Aduhelm absent peer-reviewed data supporting the treatment's clinical effectiveness; and (v) the VA's willingness and capacity to cover and administer Aduhelm for its beneficiaries.

162. According to the Securities Amended Complaint, FE 1 was among a team that used a customer relationship management system known as Jevelin and, later, Veeva and Qliksense, to evaluate potential treatment sites and track their "readiness" using five metrics: (i) potential patient demand for Aduhelm; (ii) the presence of necessary specialists to administer treatment and monitor patients; (iii) the ability for the site to confirm amyloid plaques in patients; (iv) the ability of the site to administer Aduhelm as an infusion; and (v) the ability of the site to use MRIs to monitor patients. (Securities Amended Complaint, ¶¶ 87-89).

163. Progress in various geographies was reported up to what Biogen designated as regional directors. Though the underlying data was tracked for all five metrics, the reports utilized a simple red (not ready) to green (ready) color-coded system. This system proved to be insufficient, and Biogen's teams soon ran into issues. Several potential treatment sites, for example, refused to move forward until they could evaluate peer-reviewed data, which Biogen could not provide. Often, sites would move forward with some aspects of the readiness process and be deemed "ready" by Biogen's teams, even though they had not yet evaluated the necessary peer-reviewed data that they required. (Securities Amended Complaint, ¶¶ 90-91).

164. According to the Securities Amended Complaint, FE 1 and FE 2 knew that certain statements by senior members of Biogen regarding site readiness were, in fact, inaccurate. Further, over the course of their employment at Biogen, FE 1 came to believe that the site readiness data included a range of inaccuracies or outright fabrications. In March 2021, FE 1 "told the Senior Director explicitly that there was no way 600 sites were ready nationally." (Securities Amended Complaint, ¶¶ 94, 109).

165. According to the Securities Amended Complaint, on April 14, 2021, FE 1, FE 2, and their teams were instructed by their supervisors to code all treatment sites administered by the VA as fully ready in Javelin, regardless of their actual status. These accounts were further confirmed by FE 7. FE 1 reported that a regular subject of discussion among co-workers was the discrepancy between what Biogen executives were telling the public versus what the employees knew to be true. FE 1, and others, raised these issues with Biogen leadership. FE 2 informed their supervisor that such coding was at odds with the reality of those treatment sites. (Securities Amended Complaint, ¶¶ 95, 102, 112, 158).

166. According to the Securities Amended Complaint, FE 2 shared FE 1's concerns about how site readiness data was reported within Biogen and sought guidance from senior leadership to define site readiness, but to no avail. (Securities Amended Complaint, ¶ 108).

167. On September 24, 2021, FE 2 received an email informing them that the ability to code sites as ready had been locked, and changes to a site's status would require supervisor input. Additionally, data in the Javelin system would transition to the new Veeva platform. FE 2 learned this was also happening to those in their position in other regions. (Securities Amended Complaint, ¶ 118).

168. With respect to issues in Aduhelm's rollout, FE 3, whose job responsibilities included evaluating infusion site assessments, believed that the real "bottleneck" to administering Aduhelm was the imaging centers where patients would receive lumbar punctures for CSF analysis. FE 3 believed that there were insufficient incentives for the imaging centers to perform lumbar punctures on potential patients because the centers would earn only around $189 for an hour-and-a-half lumbar puncture procedure, as compared to potentially earning $2,500 to perform a one-hour PET scan. FE 3 stated that it was widely acknowledged within the Company that the facilities performing lumbar punctures were a major bottleneck in diagnosing patients to begin receiving Aduhelm, and that meetings to address the issue occurred "all the time" in 2021. These accounts were further confirmed by FEs 5, 6 and 7. (Securities Amended Complaint, ¶¶ 125, 156).

169. According to FE 3, many neurologists were reluctant to prescribe Aduhelm because of the controversial approval process and the lack of data supporting its efficacy. According to FE 3, the controversy surrounding the therapy's approval instilled doubt in the minds of many providers, who insisted on evaluating peer reviewed data prior to prescribing it. (Securities Amended Complaint, ¶ 127).

170. According to the Securities Amended Complaint, FE 4 oversaw the account liaisons working to assess site readiness, which was based on an "extremely comprehensive" list of approximately seventy questions built into the Javelin system. FE 4 stated that executives within the Alzheimer's division exerted "a ton of pressure" on liaison managers to turn sites green, to signal their readiness, as quickly as possible. Certain sites, such as those associated with the VA, were turned green despite the fact that the VA had not allowed them access due to the Covid pandemic. (Securities Amended Complaint, ¶¶ 129-34).

171. According to the Securities Amended Complaint, in January or February 2021, FE 4 learned that Dr. Brad Dickerson, head of neurology at Mass General Brigham, conveyed to Biogen that he did not believe Aduhelm would be an effective treatment. FE 4 held the belief that the opinion of such a key opinion leader at a large institution would constitute "earth shattering" news. Further, Dr. Andrew Budson, a key Alzheimer's opinion leader with Boston University and the VA Boston Healthcare System, conveyed to Biogen's medical science liaison, Johannah Venturini, that he did not support Aduhelm for the VA's formulary. Venturini then relayed this information to FE 4 as early as March 2021, well before the Company's statements on the issue during the July 8, 2021 Conference Call. (Securities Amended Complaint, ¶¶ 138-40).

172. With respect to the imaging centers, FE 5, who worked directly with doctors to teach the benefits of Aduhelm, stated that doctors who refused to prescribe Aduhelm were concerned with the requirement for a lumbar puncture, the cost of the therapy, and its unimpressive study results. Particularly, the requirement for a lumbar puncture was a "no go" for doctors, especially those with elderly patients. FE 5 also received feedback from doctors that Aduhelm's price was far too high and that patients would be unable to pay. (Securities Amended Complaint, ¶¶ 142-45).

173. According to the Securities Amended Complaint, FE 6 was able to see that all major hospitals in the Boston area were coded as green, even though they knew this to be inaccurate. For example, prior to Aduhelm's launch, Tufts Medical Center was coded as "ready to treat," even though it had already clearly informed Biogen of its unwillingness to prescribe the treatment and that it was unlikely to ever support the therapy. Further, FE 6 corroborated the accounts of FE 3 and FE 5 that a significant reason for opposition to Aduhelm was the need for a lumbar puncture to confirm amyloid beta. FE 6 also confirmed that VA sites were coded green, even though the VA had not allowed the necessary reviews due to the Covid pandemic. (Securities Amended Complaint, ¶¶ 152-54).

174. According to the Securities Amended Complaint, FE 8, who worked directly with potential prescribers, believed that Biogen's senior leadership "absolutely knew" that the treatment was divisive, likely due to skepticism about the underlying data and the PCNS Advisory Committee's unanimous recommendation against FDA approval of the treatment. FE 8 believed that these issues negatively impacted Aduhelm's commercial prospects and performance following the FDA's approval. (Securities Amended Complaint, ¶¶ 160).

175. As a result of the Individual Defendants' wrongful acts and omissions, the Company has been substantially harmed.

Biogen's Violations of the False Claims Act

176. Biogen offers several products to treat patients with multiple sclerosis and hemophilia, costing patients between $50,000 to $80,000 per year. In 2015, just three of these drugs, Tecfidera, Avonex, and Tysabri, accounted for more than $8.4 billion in revenues for the Company. This revenue included more than $1.1 billion in Medicare claims, $219 million in Medicaid claims, and millions more in other government-funded coverage claims.

177. Each year, Biogen utilizes a Free Drug Program to provide free drugs to thousands of patients who have no insurance coverage, whether because they have no insurance, or their insurance plan denies or limits coverage. Patients who cannot or will not pay for Biogen's drugs themselves are provided the drug for free, often resulting in prescription of the drug when it is of questionable therapeutic value. The primary purpose of the Free Drug Program is to "seed" Biogen's commercial patient population. The Company understands and, to an extent, relies on the fact that once a patient starts a particular therapy, he or she will likely continue on that therapy. The company further anticipates that a large portion of its free-drug patients will eventually obtain coverage and convert to being profitable commercial patients, often under certain government programs such as Medicare, state Medicaid programs, VA health care benefits, or the Federal Employee Health Benefits Program.

178. Such programs may be beneficial for patients, but also run the risk of abuse by large pharmaceutical companies such as Biogen in attempts to expand a drug's customer base. Accordingly, these programs are subject to strict and carefully laid-out rules governing their administration. Since at least 2003, the HHS OIG has made clear that drug manufacturers are subject to special proscriptions, including the prohibition of directly or indirectly funding the cost-sharing obligations of patients who have government-sponsored medical coverage.

179. In a special advisory bulletin released on May 30, 2014, entitled "Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs," the HHS OIG reiterated that "pharmaceutical manufacturers and their affiliates should not exert any direct or indirect influence or control over the charity or its assistance program."

180. More recently, OIG has identified "problematic 'seeding' programs in which a manufacturer might offer a drug for free or at a greatly reduced cost to induce a patient onto that

drug and for the patient to obtain subsequent supplies that would be billed to Federal health care programs."

181. On February 3, 2017, the Whistleblower Action was filed in the United States District Court for the District of Massachusetts, alleging, among other things, that the Company engaged in an illegal "seeding" program in violation of the AKS.

182. The Whistleblower Complaint alleges that the Company intentionally provided illegal remuneration in the form of inducing patients to take its drugs for free so that they would later submit claims for the drugs to government programs, thus "seeding" its commercial payment population and ultimately resulting in higher payments to Biogen.

183. According to the Whistleblower Complaint, the Company then engages in a scheme to "sweep" these free-drug patients to government programs. First, the Company performed benefits investigations to identify which patients in the Free Drug Program were eligible for Medicare or other government programs. Biogen's Patient Services Department ("Patient Services") would then contact these patients to obtain their consent to being placed on the government program and informed them that the change would cost them nothing. (Whistleblower Complaint, ¶ 99).

184. Biogen was aware that it could not pay for the patients' copays directly once they were switched to the government programs, because that would be a clear violation of the AKS. Instead, Patient Services would coordinate with charity patient assistance programs ("PAPs") to ensure there would be copay coverage for the Medicare-eligible patients. According to the Whistleblower Complaint, in a direct *quid pro quo*, Biogen obtained commitments from the charities to cover specific patients' copays by awarding them grants. Within a couple of days after the grants were awarded, the free-drug patients were then "swept" to Medicare and enrolled in that

charity's PAP to cover the patients' co-pays. (Whistleblower Complaint, ¶ 100).

185. According to the Whistleblower Complaint, the PAPs also provided Biogen with detailed information and regular status reports, allowing the Company to correlate its funding and actions to direct its support to patients that were using the Company's drugs. As most PAPs operate on a first-come, first-served basis, the information sharing and coordination were critical to the success of the scheme and allowed Biogen to ensure its donations would actually be used for the patients it swept into the programs. (Whistleblower Complaint, ¶¶ 103, 105).

186. The detailed information further allowed Biogen to track the success of the scheme and its impact on the Company's bottom line. For example, one 2012 analysis explained that there was a $4.5 million upside in revenue for a separate drug, Avonexm, due in part to an "[i]mproved execution on Access program," which swept 500 patients more than had been forecast. (Whistleblower Complaint, ¶ 122).

187. By 2015, in response to growing concerns over increased HHS OIG scrutiny, the Company analyzed its return on investment ("ROI") of charity donations for the fourth quarter of 2014 in order to justify continuing the commitments. The Company wanted to ensure it would be getting a sufficient return on its "investments" in the form of donations to the charities and determine what would be required to sweep enough patients for the year. The resulting analysis found that 90% of the Company's contributions to the PAPs would be directed to patients taking Biogen durgs, resulting in an expected ROI of $18 for every dollar granted to the charities. (Whistleblower Complaint, ¶ 122).

188. In December 2020, the DOJ intervened in the Whistleblower Action against Biogen. On December 17, 2020, the DOJ announced in a press release that the Company had agreed to pay a $22 million fine to resolve the allegations in the Whistleblower Action. In the press

release, First Assistant United States Attorney Nathaniel R. Mendell was quoted as saying, "[b]y treating the foundations simply as conduits to pay the co-pays of its own patients, Biogen violated the anti-kickback statute and undermined Medicare's co-pay structure, which Congress intended as a safeguard against inflated drug prices."

189. The December 17, 2020 press release continued:

> Biogen sells Avonex and Tysabri, which are approved for treatment of multiple sclerosis. The government alleged that Biogen engaged in a prohibited kickback scheme by using two foundations, which claim 501(c)(3) status for tax purposes, as conduits to pay the copay obligations of Medicare patients to induce those patients to purchase Medicare-reimbursed Avonex and Tysabri prescriptions. As part of the scheme, Biogen identifed for its vendor, Advanced Care Scripts (ACS), certain patients in Biogen's Avonex or Tysabri free drug program. Biogen then worked with ACS to transfer these patients to the foundations, which received contemporaneous payments from Biogen and then covered the costs of Medicare copays for most or all of these patients. Medicare paid the remaining portion of the patients' Avonex or Tysabri claims. The government alleged that Biogen engaged in this conduct in the frst quarter of 2011 for certain Avonex patients, and in the second and third quarters of 2012 and 2013 for certain Tysabri patients.

190. In a separate settlement announced the same day, ACS agreed to pay $1.4 million to resolve claims against it for its role in the scheme.

191. On September 24, 2021, Humana, an administrator of Medicare Part D insurance plans on behalf of the federal government for millions of members filed the complaint in the Humana Action. The Humana Action alleges that Biogen's violations of the RICO Act, 18 U.S.C. §1962 (c) and (d), the AKS, and various state laws caused Humana to pay for prescriptions that it would otherwise not have reimbursed, and to pay more for prescriptions than it otherwise might have paid. Further, the Humana Action alleges that Biogen actively and fraudulently concealed the existence of its illegal scheme

192. As a result of the fraudulent kickback schemes and subsequent damages on Medicare administrators such as Humana, the Company has been exposed to substantial class-wide liability.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

193. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties by the Individual Defendants.

194. Biogen is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would otherwise not have.

195. Plaintiff is a current shareholder of Biogen and was a continuous shareholder of the Company during the period of the Individual Defendants' wrongdoing alleged herein. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and retained counsel competent and experienced in derivative litigation.

196. Given the factual allegations set forth herein, Plaintiff has not made a demand on the Board to bring this action against the Individual Defendants. A pre-suit demand on the Board would be futile as there is reason to doubt that a majority of the members of the Board are capable of making an independent and/or disinterested decision to initiate and vigorously pursue this action. As set forth herein, Plaintiff has adequately alleged that there is reason to doubt that the eleven current directors of Biogen are capable of disinterestedly and independently considering a demand to initiate and vigorously prosecute this action.

197. The Individual Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

198. Each of the Individual Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's shareholders or recklessly and/or with gross negligence disregarded the wrongs

complained of herein and are therefore not disinterested parties.

199. Each of the Individual Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

200. Each of the Individual Defendants, as directors of Biogen, were required to, but failed to, take action when presented with red flags regarding misconduct in connection with the Company's sales and marketing practices, clinical trials, and applications for FDA approval.

201. Moreover, the Individual Defendants knew or should have known that the Company was engaging in an illegal kickback scheme that used its free-drug program and so-called financial assistance charities as conduits to induce and steer thousands of patients on to its drugs. The Individual Directors were required to investigate and take action to prevent damage to Biogen, its shareholders, and customers, but failed to take timely action, ignoring all red flags pointing to deficiencies in the Company's internal controls and corporate governance procedures. Furthermore, the Individual Defendants have failed to make any attempts to recoup the costs from those responsible for the illegal scheme, despite the public announcement by the DOJ on December 17, 2020, disclosing the Company's role in the scheme and $22 million payment to settle the claims against it.

202. Furthermore, Defendant Vounatsos is named as a defendant in the Securities Class Action and, as such, is incapable of considering a demand to commence and vigorously prosecute this action with independence and disinterest.

203. Additionally, each of the Individual Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the Company.

COUNT I

Against The Individual Defendants For Violations of § 10(b) of the Exchange Act and Rule 10b-5

204. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

205. The Individual Defendants violated § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

206. The Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were materially false and misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

207. The Individual Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Biogen common stock.

208. The Individual Defendants acted with scienter because they (a) knew that the public documents and statements issued or disseminated in the name of Biogen were materially false and misleading; (b) knew that such statements or documents would be issued or disseminated to the

investing public; and (c) knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws.

209. The Individual Defendants, by virtue of their receipt of information reflecting the true facts of Biogen, their control over, and/or receipt and/or modification of Biogen's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning Biogen, participated in the fraudulent scheme alleged herein.

210. As a result of the foregoing, the market price of Biogen common stock was artificially inflated. In ignorance of the falsity of the statements, shareholders relied on the statements described above and/or the integrity of the market price of Biogen common stock in purchasing Biogen common stock at prices that were artificially inflated as a result of these false and misleading statements.

211. As a result of the wrongful conduct alleged herein, the Company has suffered significant damages, including the costs and expenses incurred in defending itself in the Securities Class Action, and reputational harm. In addition, as a consequence of their breach of fiduciary duties, the Individual Defendants have exposed the Company to millions of dollars in potential class-wide damages in the Securities Class Action.

COUNT II

Against The Individual Defendants For Breach Of Fiduciary Duty

212. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

213. The Individual Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed the Company the highest obligation

of good faith, fair dealing, loyalty, and due care.

214. The Individual Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

215. The Individual Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Individual Defendants breached their fiduciary duties of loyalty and good faith by permitting the use of inadequate practices and procedures to guide the truthful dissemination of Company news to the investing public and to the Company's shareholders, allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. The Individual Defendants further failed to implement and maintain an effective system of internal controls to ensure that the Company was complying with all laws, rules, and regulations governing Biogen's core operations. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

216. As a direct and proximate result of the Individual Defendants' failure to fulfill their fiduciary obligations, the Company has sustained significant damages.

217. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company. As a direct and proximate result of the Individual Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs incurred in defending itself in the Securities Class Action, exposing the Company to millions of dollars in potential class-wide damages in the Securities Class Action, and damage to the share price of the Company's stock,

resulting in an increased cost of capital, and reputational harm.

COUNT III

Against The Individual Defendants For Aiding and Abetting Breach of Fiduciary Duty

218. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

219. By encouraging and accomplishing the illegal and improper transactions alleged herein and concealing them from the public, the Individual Defendants have each encouraged, facilitated, and advanced their breaches of their fiduciary duties. In so doing, the Individual Defendants have each aided and abetted, conspired, and schemed with one another to breach their fiduciary duties, waste the Company's corporate assets, and engage in the ultra vires and illegal conduct complained of herein.

220. Plaintiff on behalf of Biogen has no adequate remedy at law.

COUNT IV

Against The Individual Defendants For Unjust Enrichment

221. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

222. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Biogen.

223. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Biogen that was tied to the performance or artificially inflated valuation of Biogen, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

224. Plaintiff, as a shareholder and a representative of Biogen, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, benefits and other compensation procured by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

225. Plaintiff on behalf of Biogen has no adequate remedy at law.

COUNT V

Against The Individual Defendants For Waste Of Corporate Assets

226. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

227. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the time period in issue. It resulted in continuous, connected, and ongoing harm to the Company.

228. As a result of the misconduct described above, the Individual Defendants wasted corporate assets by, inter alia: (a) paying and colleting excessive compensation and bonuses; and (b) incurring potentially millions of dollars of legal liability and/or legal costs, including defending the Company and its officers against the Securities Action.

229. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

230. Plaintiff on behalf Biogen has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Awarding money damages against all Individual Defendants, jointly and severally, for all losses and damages suffered as a result of the acts and transactions complained of herein,

together with pre-judgment interest, molded in a fashion to ensure the Individual Defendants do not participate therein or benefit thereby;

B. Directing all Individual Defendants to account for all damages caused by them and all profits and special benefits and unjust enrichment they have obtained as a result of their unlawful conduct, including all salaries, bonuses, fees, stock awards, options and common stock sale proceeds, and imposing a constructive trust thereon;

C. Directing Biogen to take all necessary actions to reform and improve its compliance, internal control systems and corporate governance practices and procedures to comply with applicable laws and protect the Company and its stockholder from a repeat of the damaging events described herein;

D. Awarding punitive damages;

E. Awarding costs and disbursements of this action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: July 21, 2022

MATORIN LAW OFFICE, LLC

By: */s/ Mitchell J. Matorin*

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